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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/583,706	04/12/2007	Yasumasa Mitani	20078.1USWO	4017

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EXAMINER	
MUMMERT, STEPHANIE KANE	
ART UNIT	PAPER NUMBER
1637	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/583,706	MITANI ET AL.	
	Examiner	Art Unit	
	STEPHANIE K. MUMMERT	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 October 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-83* is/are pending in the application.

4a) Of the above claim(s) *8-83* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :9/25/06;6/3/08;9/10/08;9/12/08;10/24/08;11/12/08;1/12/09;4/7/09;4/20/09;6/25/09;7/15/09;8/26/09.

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group 1, claims 1-7 in the reply filed on October 23, 2009 is acknowledged.

Claims 8-83 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on October 23, 2009.

Claims 1-7 are pending and will be examined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Rabbani et al. (EP0971039A2, published January 12, 2000). Rabbani teaches a set of primers for the amplification of a target (Abstract).

With regard to clain 1, Rabbani teaches a primer set comprising at least two primers that allows a target nucleic acid sequence to be amplified, wherein a first primer included in the primer set contains, in its 3' end portion, a sequence (Ac') that hybridizes to a sequence (A) located in the 3' end portion of the target nucleic acid sequence, and also contains, on the 5' side of the sequence (Ac'), a sequence (B') that hybridizes to a complementary sequence (Bc) to a

sequence (B) that is present on the 5' side with respect to the sequence (A) in the target nucleic acid sequence (Figure 4, step 1 and 2, where the first primer includes a sequence F at 3' end complementary to the F' portion at the 3' end of the template, and a sequence E' that is complementary to the E sequence that is 5' with respect to F in the target; and where F and E are equivalent to and in the same format and locations as the regions designated A, B, C, D in the template/target), and a second primer included in the primer set contains, in its 3' end portion, a sequence (Cc') that hybridizes to a sequence (C) located in the 3' end portion of a complementary sequence to the target nucleic acid sequence, and also contains, on the 5' side of the sequence (Cc'), a folded sequence (D-Dc') that contains, on the same strand, two nucleic acid sequences that hybridize to each other (Figure 1, step 3, were the second primer includes a region C-C' which forms a folded sequence at the 5' end of the primer and a sequence D' in the 3' end of the primer which hybridizes to the sequence D on the template).

With regard to claim 2, Rabbani teaches an embodiment of claim 1, further comprising a third primer that hybridizes to the target nucleic acid sequence or the complementary sequence thereto, wherein the third primer does not compete with other primers for hybridization to the target nucleic acid sequence or the complementary sequence thereto (Figure 2, step 1, primer F, which binds to an extension product of the second primer of claim 1, including the folded sequence).

With regard to claim 3, Rabbani teaches an embodiment of claim 1, wherein in the first primer, when no intervening sequence is present between the sequence (Ac') and the sequence (B'), a ratio (X-Y)/X is in a range of-1.00 to 1.00, where X denotes the number of bases contained in the sequence (Ac') while Y indicates the number of bases contained in a region flanked by the

sequence (A) and the 30 sequence (B) in the target nucleic acid sequence, and when an intervening sequence is present bet the sequence (Ac') and the sequence (B') in the primer, a ratio {X-(YY')}/Xis in a range of-l.00 to 1.00, where X and Y denote the same as described above, and Y' indicates the number of bases contained in the intervening sequence (see Example 1, p. 21, paragraphs 117-118, where the first primer has an F region (corresponding to Ac') of 29 or 30 nucleotides and since there is no intervening sequence between F and E (corresponding to A and B), where the flanking region is 0 nucleotides. Therefore, (X-Y)/X = (29-0)/29 = 1).

With regard to claim 4, Rabbani teaches the second primer, the folded sequence (D-Dc') has a length of 2 to 1000 nucleotides (p. 21, paragraph 118, where the stem loop structure depicted in Figure 4, where the basepair stems are 30 bp and 29 or 30 bp loops, leading to a folded sequence of approximately 90 bp).

With regard to claim 5, Rabbani teaches an embodiment of claim 1, wherein at least one primer included in the primer set has a solid-phase support or a site that can bind to a solid-phase support (p. 19, paragraph 103, where the primer includes a group that is useful for attachment of signal generating groups which can also be useful for binding to other formats, including a solid support).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rabbani et al. (EP0971039A2, published January 12, 2000) as applied to claims 1-5 above in view of Pastinen et al. (Genome Research, 1997, vol. 7, p. 606-614). Rabbani teaches a set of primers for the amplification of a target (Abstract).

With regard to claim 5, Rabbani teaches an embodiment of claim 1, wherein at least one primer included in the primer set a site that can bind to a solid-phase support (p. 19, paragraph 103, where the primer includes a group that is useful for attachment of signal generating groups which can also be useful for binding to other formats, including a solid support).

Regarding claim 5, while Rabbani teaches a site for attachment to a solid phase support, Rabbani does not teach attachment to a solid phase support. Pastinen teaches attachment of primers to solid phase support prior to mini-sequencing reactions (Abstract).

With regard to claim 5, Pastinen teaches an embodiment of claim 1, wherein at least one primer included in the primer set has a solid-phase support or a site that can bind to a solid-phase support (p. 610, col. 2, where oligonucleotide primers were spotted onto a glass slide, attached by a 5' amino group).

With regard to claim 6, Pastinen teaches an embodiment of claim 5, wherein the solid-phase support is one selected from the group consisting of a water-insoluble organic polymer support, a water-insoluble inorganic polymer support, a synthetic polymer support, a phase transition support, a metal colloid, and a magnetic particle (p. 610, col. 2, where oligonucleotide primers were spotted onto a glass slide, attached by a 5' amino group).

With regard to claim 7, Pastinen teaches an embodiment of claim 5, wherein the site that can bind to a solid-phase support is selected from the group consisting of biotin, avidin,

streptoavidin, an antigen, an antibody, a ligand, a receptor, a nucleic acid, and a protein (p. 610, col. 2, where oligonucleotide primers were spotted onto a glass slide, attached by a 5' amino group).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have adjusted the teachings of Rabbani to include the attachment of primers to solid phase supports as taught by Pastinen to arrive at the claimed invention with a reasonable expectation for success. As taught by Pastinen, "mutations are detected by extending immobilized primers that anneal to their template sequences immediately adjacent to the mutant nucleotide positions with single labeled dideoxynucleoside triphosphates using a DNA polymerase" (Abstract). Pastinen also teaches, "Our results show that single-nucleotide primer extension is an excellent reaction principle for multiplex detection of mutations" (p. 607, col. 2). Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to have adjusted the teachings of Rabbani to include the attachment of primers to solid phase supports as taught by Pastinen to arrive at the claimed invention with a reasonable expectation for success.

Conclusion

No claims are allowed. All claims stand rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEPHANIE K. MUMMERT whose telephone number is (571)272-8503. The examiner can normally be reached on M-F, 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Stephanie K. Mummert/
Examiner, Art Unit 1637

SKM